THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION (FORM CMS-116)

INSTRUCTIONS FOR COMPLETION

CLIA requires every facility that tests human specimens for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, a human being to meet certain Federal requirements. If your facility performs tests for these purposes, it is considered, under the law, to be a laboratory. CLIA applies even if only one or a few basic tests are performed, and even if you are not charging for testing. In addition, the CLIA legislation requires financing of all regulatory costs through fees assessed to affected facilities.

The CLIA application (Form CMS-116) collects information about your laboratory's operation which is necessary to determine the fees to be assessed, to establish baseline data and to fulfill the statutory requirements for CLIA. This information will also provide an overview of your facility's laboratory operation. All information submitted should be based on your facility's laboratory operation as of the date of form completion. **NOTE: WAIVED TESTS ARE NOT EXEMPT FROM CLIA. FACILITIES PERFORMING ONLY THOSE TESTS CATEGORIZED AS WAIVED MUST APPLY FOR A CLIA CERTIFICATE OF WAIVER.**

THE GENERAL INFORMATION SECTION AND ALL APPLICABLE SECTIONS MUST BE COMPLETED. INCOMPLETE APPLICATIONS CANNOT BE PROCESSED AND WILL BE RETURNED TO THE FACILITY. PRINT LEGIBLY OR TYPE INFORMATION.

I. GENERAL INFORMATION

For an initial applicant, the CLIA identification number should be left blank. The number will be assigned when the application is processed.
Be specific when indicating the name of your facility, particularly when it is a component of a larger entity; e.g., respiratory therapy department in XYZ Hospital. For a physician's office, this may be the name of the physician. **NOTE: The information provided is what will appear on your certificate.**

Facility street address must be the actual physical location where testing is performed, including floor, suite and/or room, if applicable. **DO NOT USE A POST OFFICE BOX NUMBER OR A MAIL DROP ADDRESS FOR THE NUMBER AND STREET OF THE ADDRESS**. If the laboratory has a separate mailing or billing address, please complete that section of the application.

II. TYPE OF CERTIFICATE REQUESTED

When completing this section, please remember that a facility holding a—

- **Certificate of Waiver** can only perform tests categorized as waived;*
- **Certificate for Provider Performed Microscopy Procedures** (PPMP) can only perform tests categorized as PPMP, or tests categorized as PPMP and waived tests;*
- **Certificate of Compliance** can perform tests categorized as waived, PPMP and moderate and/or high complexity tests provided the applicable CLIA quality standards are met; and
- **Certificate of Accreditation** can perform tests categorized as waived, PPMP and moderate and/or high complexity tests provided the laboratory is currently accredited by an approved accreditation organization.**

*A current list of waived and PPMP tests may be obtained from your State agency. Specific test system categorizations can also be reviewed via the Internet on *www.cdc.gov/phppo/dls/*.

****If you are applying for a Certificate of Accreditation, you must provide evidence of accreditation for your laboratory by an approved accreditation organization for CLIA purposes or evidence of application for such accreditation within 11 months after receipt of your Certificate of Registration.**

III. TYPE OF LABORATORY

Select the type of laboratory designation that is most appropriate for your facility from the list provided. If you cannot find your designation within the list, contact your State agency for assistance.

IV. HOURS OF ROUTINE OPERATION

Provide only the times when actual laboratory testing is performed in your facility.

V. MULTIPLE SITES

You can only qualify for the multiple site provision (more than one site under one certificate) if you meet one of the CLIA regulatory exceptions outlined on the form.

VI. WAIVED TESTING

Include only the estimated annual volume for those tests that are waived.

VII. NON-WAIVED TESTING *(Including PPMP)*

Follow the specific instructions on page 3 of the Form CMS-116 when completing this section. (Note: The Accrediting Organization column should reflect accreditation information for CLIA purposes only; e.g., JCAHO, etc.).

VIII. TYPE OF CONTROL

Select the code which most appropriately describes your facility. Proprietary/for profit entities must choose "04".

IX. DIRECTOR AFFILIATION WITH OTHER LABORATORIES

List all other facilities for which the director is responsible. Note that for a Certificate of PPMP, Certificate of Compliance or Certificate of Accreditation, an individual can only serve as the director for no more than five certificates.

X. INDIVIDUALS INVOLVED IN LABORATORY TESTING

Self explanatory

Once the completed Form CMS-116 has been returned to the applicable State agency and it is processed, a fee remittance coupon will be issued. The fee remittance coupon will indicate your CLIA identification number and the amount due for the certificate, and if applicable the compliance (survey) or validation fee. If you are applying for a Certificate of Compliance or Certificate of Accreditation, you will initially pay for and receive a Registration Certificate. A Registration Certificate permits a facility requesting a Certificate of Compliance to perform testing until an onsite inspection is conducted to determine program compliance; or for a facility applying for a Certificate of Accreditation, until verification of accreditation by an approved accreditation organization is received by CMS.

If you need additional information concerning CLIA, or if you have questions about completion of this form, please contact your State agency.

Form Approved
OMB No. 0938-0581

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA) APPLICATION FOR CERTIFICATION

I. GENERAL INFORMATION

❑ Initial Application ❑ Change in Certification Type	CLIA Identification Number _____D_____ *(If an initial application leave blank, a number will be assigned)*
Facility Name	Federal Tax Identification Number Telephone No. *(Include area code)* Fax No. *(Include area code)*
Facility Address — *Physical Location of Laboratory (Building, Floor, Suite if applicable.)*	Mailing/Billing Address *(If different from street address, include attention line and/or Building, Floor, Suite)*
Number, Street *(No P.O. Boxes)*	Number, Street
City State ZIP Code	City State ZIP Code
Name of Director *(Last, First, Middle Initial)*	

II. TYPE OF CERTIFICATE REQUESTED *(Check one)*

❑ Certificate of Waiver *(Complete Sections I – VI and VIII – X)*

❑ Certificate for Provider Performed Microscopy Procedures *(PPMP) (Complete Sections I – X)*

❑ Certificate of Compliance *(Complete Sections I – X)*

❑ Certificate of Accreditation (Complete Sections I through X) and indicate which of the following organization(s) your laboratory is accredited by for CLIA purposes, or for which you have applied for accreditation for CLIA purposes

❑ JCAHO ❑ AOA ❑ AABB

❑ CAP ❑ COLA ❑ ASHI

If you are applying for a Certificate of Accreditation, you must provide evidence of accreditation for your laboratory by an approved accreditation organization for CLIA purposes or evidence of application for such accreditation within 11 months after receipt of your Certificate of Registration.

III. TYPE OF LABORATORY *(Check the one most descriptive of facility type)*

- ❑ 01 Ambulatory Surgery Center
- ❑ 02 Community Clinic
- ❑ 03 Comp. Outpatient Rehab. Facility
- ❑ 04 Ancillary Testing Site in Health Care Facility
- ❑ 05 End Stage Renal Disease Dialysis Facility
- ❑ 06 Health Fair
- ❑ 07 Health Main. Organization
- ❑ 08 Home Health Agency
- ❑ 09 Hospice
- ❑ 10 Hospital
- ❑ 11 Independent
- ❑ 12 Industrial
- ❑ 13 Insurance
- ❑ 14 Intermediate Care Facility for Mentally Retarded
- ❑ 15 Mobile Laboratory
- ❑ 16 Pharmacy
- ❑ 17 School/Student Health Service
- ❑ 18 Skilled Nursing Facility/Nursing Facility
- ❑ 19 Physician Office
- ❑ 20 Other Practitioner *(Specify)* _____
- ❑ 21 Tissue Bank/Repositories
- ❑ 22 Blood Banks
- ❑ 23 Rural Health Clinic
- ❑ 24 Federally Qualified Health Center
- ❑ 25 Ambulance
- ❑ 26 Public Health Laboratories _____
- ❑ 27 Other _____

Is this a Medicare/Medicaid certified facility? ❑ Yes ❑ No

If yes, indicate Medicare provider number _____ Medicaid number _____

IV. HOURS OF LABORATORY TESTING *(List times during which **laboratory testing** is performed)*

	SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
FROM: AM							
PM							
TO: AM							
PM							

(For multiple sites, attach the additional information using the same format.)

V. MULTIPLE SITES *(must meet one of the regulatory exceptions to apply for this provision)*

Are you applying for the multiple site exception?

❑ No. If no, go to section VI. ❑ Yes. If yes, provide total number of sites under this certificate_____ and complete remainder of this section.

Indicate which of the following regulatory exceptions applies to your facility's operation.

Is this a not-for-profit or Federal, State or local government laboratory engaged in limited (not more than a combination of 15 moderate complexity or waived tests per certificate) public health testing and filing for a single certificate for multiple sites? ❑ Yes ❑ No

If yes, list name, address and tests performed for each site below.

Is this a hospital with several laboratories located at contiguous buildings on the same campus within the same physical location or street address and under common direction that is filing for a single certificate for these locations? ❑ Yes ❑ No

If yes, list name or department, location within hospital and specialty/subspecialty areas performed at each site below.

If additional space is needed, check here ❑ and attach the additional information using the same format.

NAME AND ADDRESS / LOCATION		TESTS PERFORMED / SPECIALTY / SUBSPECIALTY
Name of Laboratory or Hospital Department		
Address/Location *(Number, Street, Location if applicable)*		
City, State, ZIP Code	Telephone Number ( )	
Name of Laboratory or Hospital Department		
Address/Location *(Number, Street, Location if applicable)*		
City, State, ZIP Code	Telephone Number ( )	
Name of Laboratory or Hospital Department		
Address/Location *(Number, Street, Location if applicable)*		
City, State, ZIP Code	Telephone Number ( )	

VI. WAIVED TESTING

Indicate the estimated **TOTAL ANNUAL TEST** volume for all waived tests performed _____

VII. NONWAIVED TESTING *(Including PPMP testing)*

If you perform testing other than or in addition to waived tests, complete the information below. If applying for one certificate for multiple sites, the total volume should include testing for ALL sites.

Place a check (✓) in the box preceding each specialty/subspecialty in which the laboratory performs testing. Enter the estimated annual test volume for each specialty. Do not include testing not subject to CLIA, waived tests, or tests run for quality control, calculations, quality assurance or proficiency testing when calculating test volume. (For additional guidance on counting test volume, see the information included with the application package.)

If applying for certificate of accreditation, indicate the name of the accreditation organization beside the applicable specialty/subspecialty for which you are accredited for CLIA compliance. (JCAHO, AOA, AABB, CAP, COLA or ASHI)

SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME	SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME
HISTOCOMPATIBILITY		_____	**HEMATOLOGY**		_____
❑ Transplant	_____		❑ Hematology	_____	
❑ Nontransplant	_____				
			IMMUNOHEMATOLOGY		_____
MICROBIOLOGY		_____	❑ ABO Group & Rh Group	_____	
❑ Bacteriology	_____		❑ Antibody Detection (transfusion)	_____	
❑ Mycobacteriology	_____		❑ Antibody Detection (nontransfusion)	_____	
❑ Mycology	_____		❑ Antibody Identification	_____	
❑ Parasitology	_____		❑ Compatibility Testing	_____	
❑ Virology	_____				
DIAGNOSTIC IMMUNOLOGY		_____	**PATHOLOGY**		_____
❑ Syphilis Serology	_____		❑ Histopathology	_____	
❑ General Immunology	_____		❑ Oral Pathology	_____	
			❑ Cytology	_____	
CHEMISTRY		_____			
❑ Routine	_____		**RADIOBIOASSAY**		_____
❑ Urinalysis	_____		❑ Radiobioassay	_____	
❑ Endocrinology	_____				
❑ Toxicology	_____		**CLINICAL CYTOGENETICS**		_____
			❑ Clinical Cytogenetics	_____	

TOTAL ESTIMATED ANNUAL TEST VOLUME _____

VIII. TYPE OF CONTROL

Enter the appropriate two digit code from the list below ____ ____ *(Enter only one code)*

VOLUNTARY NONPROFIT	FOR PROFIT	GOVERNMENT	
01 Religious Affiliation	04 Proprietary	05 City	08 Federal
02 Private		06 County	09 Other Government
03 Other _____ *(Specify)*		07 State	_____ *(Specify)*

IX. DIRECTOR AFFILIATION WITH OTHER LABORATORIES

If the director of this laboratory serves as director for additional laboratories that are separately certified, please complete the following:

NAME OF LABORATORY	ADDRESS	CLIA IDENTIFICATION NUMBER

X. INDIVIDUALS INVOLVED IN LABORATORY TESTING

Indicate the total number of individuals involved in laboratory testing (directing, supervising, consulting or testing). Do not include individuals who only collect specimens or perform clerical duties. For nonwaived testing, only count an individual one time, at the **highest** laboratory position in which they function. (Example: Pathologist serves as director, technical supervisor and general supervisor. This individual would only be counted once (under director).)

A. WAIVED TESTING

Total No. of Individuals _____

B. NONWAIVED TESTING *(Including PPMP testing)*

Total No. of Individuals _____
Director _____
Clinical consultant _____
Technical consultant _____
Cytotechnologist _____
Technical supervisor _____
General supervisor _____
Testing personnel _____

ATTENTION: READ THE FOLLOWING CAREFULLY BEFORE SIGNING APPLICATION

Any person who intentionally violates any requirement of section 353 of the Public Health Service Act as amended or any regulation promulgated thereunder shall be imprisoned for not more than 1 year or fined under title 18, United States Code or both, except that if the conviction is for a second or subsequent violation of such a requirement such person shall be imprisoned for not more than 3 years or fined in accordance with title 18, United States Code or both.

Consent: The applicant hereby agrees that such laboratory identified herein will be operated in accordance with applicable standards found necessary by the Secretary of Health and Human Services to carry out the purposes of section 353 of the Public Health Service Act as amended. The applicant further agrees to permit the Secretary, or any Federal officer or employee duly designated by the Secretary, to inspect the laboratory and its operations and its pertinent records at any reasonable time and to furnish any requested information or materials necessary to determine the laboratory's eligibility or continued eligibility for its certificate or continued compliance with CLIA requirements.

SIGNATURE OF OWNER/DIRECTOR OF LABORATORY *(Sign in ink)*	DATE

LABORATORY TEST LIST FOR WAIVED AND PPMP TESTING

Facility Name:	CLIA #
Name of Person Completing Form:	
Laboratory Director's Signature: .	Date:

Please list the name of the waived test in the column on the left side and list the name of the corresponding kit and/or instrument and manufacturer in the column on the right side. **Ex- left column: whole blood glucose, right column: Bayer Diagnostics Elite Blood Glucose Meter and Test Strips.** If applicable, please check off the Provider Performed Microscopy Procedures performed.

ANALYTE / LABORATORY TEST	INSTRUMENT AND/OR KIT USED FOR TESTING

PROVIDER PERFORMED MICROSCOPY PROCEDURES	*EDUCATION
____ Wet Mounts; including vaginal, cervical or skin specimens	
____ All Potassium Hydroxide (KOH) preparations	
____ Pinworm Exams	
____ Fern Test	
____ Post-coital direct, qualitative exams of vaginal or cervical mucous	
____ Urinalysis; microscopic only	
____ Urinalysis; non-automated with microscopy	
____ Urinalysis; automated with microscopy	
____ Two or Three glass test	
____ Fecal leukocyte exam	
____ Semen Analysis; presence and/or motility of sperm	
____ Nasal Smears for Eosinophils	
* Education of all persons performing PPMP tests (i.e. MD, DO, PA, NP)	

INSTRUCTIONS FOR COMPLETING DISCLOSURE OF OWNERSHIP AND CONTROL INTEREST STATEMENT (Form -1513)

SPECIAL INSTRUCTIONS FOR CLIA LABORATORIES

All CLIA laboratories must complete Part I through VII(b) of this form. Failure to submit requested information may result in the suspension or revocation of any CLIA certificate or denial of application for prospective laboratories.

General Instructions

For definitions, procedures and requirements, refer to the appropriate Regulations:

CLIA	- 42CFR 493
Title XVIII	- 42CFR 420 200-206
Title XIX	- 42CFR 455 100-106
Title XX	- 45CFR 228 72-73

Please answer all questions as of the current date. If the yes block for any item is checked, list requested additional information under the Remarks Section on page 2, referencing the item number to be continued. If additional space is needed use an attached sheet.

Return the original to the State agency, retain a copy for your files.

This form is to be completed upon request. Any substantial delay in completing the form should be reported to the State survey agency.

DETAILED INSTRUCTIONS

These instructions are designed to clarify certain questions on the form. Instructions are listed in question order for easy reference. No instructions have been given for questions considered self explanatory.

IT IS ESSENTIAL THAT ALL APPLICABLE QUESTIONS BE ANSWERED ACCURATELY AND THAT ALL INFORMATION BE CURRENT.

Item I – Under identifying information specify in what capacity the entity is doing business as (DBA), for example, name of trade or corporation.

Item II – Self-explanatory.

Item III – For CLIA purposes, list the names of all individuals and organizations having direct or indirect ownership interest, or controlling interest in the disclosing entity.

Direct ownership interest is defined as the possession of stock, equity in capital or any interest in the profits of the disclosing entity. A disclosing entity is the entity that is providing laboratory services.

Indirect ownership interest is defined as ownership interest in an entity that has direct or indirect ownership interest in the disclosing entity.

Controlling interest is defined as the operational direction of management of a disclosing entity which may be maintained by any or all of the following devices: the ability or authority, expressed or reserved, to amend or change the corporate identity (i.e., joint venture agreement, unincorporated business status) of the disclosing entity; the ability or authority to nominate or name members of the Board of Directors or Trustees of the disclosing entity, the ability or authority, expressed or reserved, to amend or change the by-laws, constitution, or other operating or management direction of the disclosing entity; the right to control any or all of the assets or other property of the disclosing entity upon the sale or dissolution of that entity; the ability or authority, expressed or reserved, to control the sale or any of all of the assets, to encumber such assets by way of mortgage or other indebtedness to dissolve the entity, or to arrange for the sale or transfer of the disclosing entity to new ownership or control.

Items IV-VII – Changes in Status

Change in status is defined as any change in management control. Examples of such changes would include: a change in Director, a change in the composition of the owning partnership which under applicable State law is not considered a change in ownership, or the hiring or dismissing of any employees with any financial interest in the facility or in an owning corporation, or any change of ownership, or contracting the operation of the facility to a management corporation or changing management corporations.

For Items IV-VII, if the yes box is checked, list additional information requested under Remarks. Clearly identify which item is being continued.

Item IV – (a & b) If there has been a change in ownership within the last year or if you anticipate a change, indicate the date in the appropriate space.

Item V – If the answer is yes, list name of the management firm and employer identification number (EIN) or the name of the leasing organization. A management company is defined as any organization that operates and manages a business on behalf of the owner of that business, with the owner retaining ultimate legal responsibility for operation of the facility.

Item VI – If the answer is yes, provide the date the change was made. Be sure to include name of the new Director.

Item VII – A chain affiliate is any free-standing health care facility that is either owned, controlled, or operated under lease or contract by an organization consisting of two or more free-standing health care facilities organized within or across State lines which is under the ownership or through any other device, control and direction of a common party. Chain affiliates include such facilities whether public, private, charitable or proprietary. They also include subsidiary organization and holding corporations.

DISCLOSURE OF OWNERSHIP AND CONTROL INTEREST STATEMENT

I. Identifying Information

Name of Entity D/B/A	CLIA No.	EIN	Telephone No. and Fax No.
Street Address	**City, County, State**		**Zip Code**

II. Answer the following questions by checking "Yes" or "No". If any of the question are answered "Yes", list names and addresses of individuals or corporations under Remarks on page 2. Identify each item number to be continued.

FOR CLIA PURPOSES

A. Are there any individuals or organizations having a direct or indirect ownership or control interest in the reporting entity that have been convicted of a criminal offense related to the involvement of such persons or organizations in any of the programs established by Titles XVIII, XIX, or XX?

☐ Yes ☐ No LB 2

B. Are there any directors, officers, agents, or managing employees of the reporting entity who have been convicted of a criminal offense related to their involvement in such programs established by Titles XVIII, XIX, or XX?

☐ Yes ☐ No LB 3

C. Are there any individuals currently employed by the reporting entity in a managerial, accounting, auditing, or similar capacity who were employed by the reporting entity's fiscal intermediary or carrier within the previous 12 months ? (Title XVIII providers only)

☐ Yes ☐ No LB 4

III. (a) List names, addresses for individuals, or the EIN for organizations having direct or indirect ownership or a controlling interest in the entity. (See instructions for definition of ownership and controlling interest.) List any additional names and addresses under "Remarks" on Page 2. If more than one individual is reported and any of these persons are related to each other, this must be reported under Remarks.

Name	Address	EIN
		LB 5

(b) Type of Entity: ☐ Sole Proprietorship ☐ Partnership ☐ Corporation LB 6
☐ Unincorporated Associations ☐ Other (Specify)

(c) If the disclosing entity is a corporation, list names, addresses of the Directors, and EINs for corporations under Remarks.

Check appropriate box for each of the following questions

(d) Are any owners of the disclosing entity also owners of other Medicare/Medicaid and/or CLIA facilities? (Example: sole proprietorship, partnership or members of Board of Directors.) If yes, list names, addresses of individuals and provider numbers and/or CLIA numbers.

☐ Yes ☐ No LB 7

Name	Address	Provider Number/CLIA Number

DISCLOSURE OF OWNERSHIP AND CONTROL INTEREST STATEMENT

IV. (a) Has there been a change in ownership or control within the last year?
If yes, give date _____ ☐ Yes ☐ No LB 8

(b) Do you anticipate any change of ownership or control within the year?
If yes, give date _____ ☐ Yes ☐ No LB 9

(c) Do you anticipate filing for bankruptcy within the year?
If yes, give date _____ ☐ Yes ☐ No LB 10

V. Is this facility operated by a management company or leased in whole or part by another organization?
If yes, give date of change in operations _____ ☐ Yes ☐ No LB 11

VI. Has there been a change in Director within the last year?
If yes, give date of change _____ ☐ Yes ☐ No LB 12
name of new Director _____ (If more than one change, list in remarks.)

VII. (a) Is this facility chain affiliated? (If yes, list name, address of Corporation and EIN)
Name EIN# ☐ Yes ☐ No LB 13

Address

LB 14

VII. (b) If the answer to Question VII.(a) is No, was the facility ever affiliated with a chain?
(If YES, list Name, Address of Corporation and EIN).
Name EIN# ☐ Yes ☐ No LB 18

Address

LB 19

WHOEVER KNOWINGLY AND WILLFULLY MAKES OR CAUSES TO BE MADE A FALSE STATEMENT OR REPRESENTATION OF THIS STATEMENT MAY BE PROSECUTED UNDER APPLICABLE FEDERAL OR STATE LAWS. IN ADDITION, KNOWINGLY AND WILLFULLY FAILING TO FULLY AND ACCURATELY DISCLOSE THE INFORMATION REQUESTED MAY RESULT IN DENIAL OF AN APPLICATION FOR A CLIA CERTIFICATE OR SUSPENSION AND/OR REVOCATION OF AN EXISTING CLIA CERTIFICATE, AS APPROPRIATE.

Name of Authorized Representative (Typed)	Title

Signature	Date

Remarks